



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-0904]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c)

Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

### **Proposed Project**

SEARCH for Diabetes in Youth Study (OMB No. 0920-0904, exp. 11/30/2014) - Revision - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

Diabetes is one of the most common chronic diseases among children in the United States. Reports of increasing frequency of both type 1 and type 2 diabetes in youth have been among the most concerning aspects of the evolving diabetes epidemic. In response to this growing public health concern, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) funded the SEARCH for Diabetes in Youth Study.

The SEARCH for Diabetes in Youth Study began in 2000 as a multi-center, epidemiological study, conducted in six geographically dispersed clinical study centers that reflected the racial and ethnic diversity of the U.S. Phases 1 (2000–2005) and 2 (2005–2010) produced estimates of the prevalence and incidence of diabetes among youth age < 20 years, according to diabetes type, age, sex, and race/ethnicity, and characterized selected acute and chronic complications of diabetes and their risk factors, as well as the quality of life and quality of health care. In Phases 1 and 2, the clinical centers and a data coordinating center were funded through cooperative agreements. The information collected at that time was not

provided directly to CDC.

Phase 3 (2011-present) builds upon previous efforts. Five clinical sites collect patient-level information that is compiled by a data coordinating center. CDC obtained OMB approval to receive the information in 2011 (SEARCH for Diabetes in Youth, OMB No. 0920-0904, exp. 11/30/2014). Phase 3 includes a case registry of youth < 20 years of age who have been diagnosed with diabetes, and a longitudinal cohort research study about SEARCH cases whose diabetes was incident in 2002 or later. To date, SEARCH Phase 3 has identified an average of 1,361 incident cases of diabetes among youth under 20 years each year of the study and has completed an average of 1,088 participant surveys each year (80% participation rate among registry study participants). As of November 2013, SEARCH Phase 3 has completed visits for 1,839 cohort study participants.

CDC plans to continue information collection for two additional years, with minor changes. Participants in the registry study will continue to complete a Medication Inventory and an Initial Participant Survey; however, the in-person study examination will be discontinued. This change will result in a decrease in burden per respondent. CDC estimates that each clinical site will identify and

register an average of 255 cases per year, for a total 1,275 cases across all sites.

No data collection changes are planned for the cohort study. CDC estimates that each clinical site will conduct follow-up on an average of 142 cases per year, for a total of 710 cases across all sites. The items collected for each case include a Health Questionnaire (Youth version), an additional Health Questionnaire (Parent version), Center for Epidemiologic Study-Depression, Quality of Care, Pediatric Quality of Life Survey (Peds QL), SEARCH Michigan Neuropathy Screening Instrument, Diabetes Eating Survey, Low Blood Sugar Survey, Supplemental Survey, Tanner Stage, Retinal Photo, Family Conflict Survey, Pediatric Diabetes Quality of Life Scale, Physical Exam, Specimen Collection, and Food Frequency Questionnaire.

Findings from the registry study will be used to estimate the incidence of diabetes in youth in the U.S. Findings from the cohort study will be used to estimate the prevalence and incidence of risk factors and complications associated with diabetes in youth, including chronic microvascular complications (retinopathy, nephropathy, and autonomic neuropathy) and selected markers of macrovascular complications (hypertension, arterial stiffness) of diabetes.

Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 4,248.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)
SEARCH Registry Study Participants	Medication Inventory	1,275	1	5/60
	Initial Participant Survey	1,275	1	10/60
SEARCH Cohort Study Participants	Health Questionnaire -Youth	710	1	15/60
	Health Questionnaire -Parent	710	1	15/60
	CES-Depression	710	1	4/60
	Quality of Care	710	1	13/60
	Peds QL	710	1	5/60
	SEARCH MNSI Neuropathy	710	1	10/60
	Diabetes Eating Survey	710	1	5/60
	Low Blood Sugar Survey	710	1	5/60
	Supplemental Survey	710	1	10/60
	Tanner Stage	710	1	5/60
	Retinal Photo	710	1	15/60
	Family Conflict Survey	710	1	5/60
	Pediatric Diabetes QOL Scale	710	1	5/60

	Physical Exam	710	1	3
	Specimen Collection	710	1	20/60
	Food Frequency Questionnaire	710	1	20/60

Science,

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[FR Doc. 2014-10618 Filed 05/08/2014 at 8:45 am; Publication Date: 05/09/2014]